

REMARKS

1. Disposition of Claims

Claims 20, 22, and 23 remain pending in this application. Claim 20 has been amended, and support for this amendment can be found, for example, in Example 4 of the specification. No new matter has been added. Reconsideration of the application in view of the amendment is respectfully requested.

2. Compliance with 35 USC 112/1 enablement

The Patent Office rejected the claims under 35 USC 112/1 as failing to meet the enablement requirement. Under MPEP 2164, the test for enablement is whether one skilled in the art could make or use the subject matter defined by the claims without undue experimentation. Under MPEP 2164.01(a), the Wands factors are to be considered in determining whether any necessary experimentation is undue. Here, the specification is enabling with respect to the claimed method of producing a bacteriophage able to delay inactivation by an animal's host defense system (HDS), comprising genetically engineering a bacteriophage to express molecules on its surface coat that delay inactivation of the bacteriophage by an animal's host defense system (HDS) through the creation of a fusion protein expressed on the surface of the bacteriophage.

i) First, there is considerable direction and guidance in the specification with respect to how to make and use the subject matter defined in the claims.

Example 4 of the specification provides ample guidance as to how to carry out the claimed method. Using the specific genetic engineering technique set forth in the claims, the inventors describe how to create a fusion protein which is expressed on the surface of the phage that then delays inactivation by an animal's host defense system (HDS).

MPEP 608.01(p) allows prophetic (or paper) examples to describe a manner and process of making invention, which has not actually been conducted. Therefore, there is adequate teaching in the specification to support the claimed invention.

ii) Second, there was a high level of skill in the art at the time the application was filed. The level of skill in the molecular biology art was that of a postdoctoral fellow working in the laboratory. *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 57 USPQ2d 1449, 1518 (D. Mass. 2001). Thus, the level of skill in the art was high.

iii) **Third, all of the methods needed to practice the invention were well known.** As of the 5 April 1994 priority date, for guidance regarding such conditions, see, for example, Sambrook, et al., 1989, *Molecular Cloning, A Laboratory Manual*, Cold Spring Harbor Laboratory Press, New York; and Ausubel et al., 1989, *Current Protocols in Molecular Biology*, Green Publishing Associates, Inc., and Wiley & Sons, Inc., New York.

iv) **Per MPEP 2164.01(a), the In re Wands Court held that the specification was enabling with respect to the claims at issue and found that “there was considerable direction and guidance” in the specification; there was “a high level of skill in the art at the time the application was filed;” and “all of the methods needed to practice the invention were well known.”** Similarly, here, as indicated above, there was considerable direction and guidance in the specification; there was a high level of skill in the art at the time the application was filed; and all of the methods needed to practice the invention were well known. Thus, here, considering all the factors related to the enablement issue, it must be concluded that it would *not* require undue experimentation to make and use the subject matter defined in the claims. Withdrawal of the rejection under 35 USC 112/1 is therefore respectfully requested.

3. Compliance with 35 USC 112/1 written description

The issue is whether the claims are in compliance with the 35 USC 112/1 written description requirement. As noted above, Example 4 of the specification provides ample guidance as to how to carry out the claimed method. Using the specific genetic engineering technique set forth in the claims, the inventors describe how to create a fusion protein which is expressed on the surface of the phage that then delays inactivation by an animal's host defense system (HDS). Thus, the claims are fully supported by the specification as written, which reasonably conveys to one of skill in the art that, at the time the application was filed, the inventors had possession of the claimed invention.

4. No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather,

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any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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